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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,201	01/22/2004	Thomas Boren	0825-0176P	3104

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,201	BOREN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 1-26.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1 is, drawn to nucleic acid based vaccine, wherein the nucleotide sequence encodes a blood group antigen binding protein, classified in class 514, subclass 44.

II. Claims 2-8, 9, 16-21, 25 are, drawn to antibodies and immunoglobulins that bind to Lewis B adhesin protein, wherein the antibodies are polyclonal/monoclonal or recombinantly produced antibodies, classified in class 530, subclass 386.

III. Claims 10-13, 14-15 are, drawn to a method of manufacturing a polyclonal immunoglobulin contained in milk, colostrum or egg yolk; a method of manufacturing a monoclonal immunoglobulin through fusing cells with a neoplastic cell line utilizing Lewis B binding adhesin protein/ and a method that further comprising transforming and expressing the monoclonal antibody by a culture of viable microorganisms, wherein the immunogen is Lewis B binding adhesin protein, classified in class 435, subclass 346.

IV. Claims 22-24 are, drawn to a method of treating or preventing H.pylori infection with a polyclonal/monoclonal or recombinant immunoglobulin/antibody composition directed to Lewis B binding adhesin protein classified in class 424, subclass 130.1 .

V. Claims 26 is, drawn to a method of treating or preventing H.pylori infection with a recombinant culture of viable microorganisms that express the coding nucleotide sequence for H.pylori Lewis B binding adhesin protein classified in class 424, subclass 200.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions include the DNA of Group I, the immunoglobulin/antibodies of Group II do not share

3. the same structural and functional characteristics, thus setting forth independent and distinct compositions based upon the structural components which evidence different functions and effects based upon what each invention binds.

4. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case: the product as claimed can be used in a materially different process of using that product, wherein the nucleotide sequence of claim 1 can be used in a method of making a protein, in a method of diagnosing Helicobacter pylori infection and in a method of screening for inhibitors for protein expression in Helicobacter pylori .

5. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the product as claimed can be made by another and materially different process, wherein immunoglobulins, monospecific antisera, and recombinant antibodies can be produced synethically based upon biochemical synthesis of the antibodies from knowledge of the amino sequence that code for the hypervariable antigen binding region of the antibodies/monospecific antisera.

6. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the antisera/antibodies/immunoglobulin/ and chimeric antibodies can be used in a method of detecting infection, in a method of purifying antigen, in a method of epitope mapping immunogenic portions of the blood group antigen binding protein.

7. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the antibodies of Group IV evidence different modes of operation, different functions, and different effects from recombinantly transformed microorganisms of Group V, wherein the recombinantly transformed microorganisms of Group V comprise a coding sequence for a blood group binding antigen and the recombinant microorganism of Group IV encodes a protein antibody that binds to an antigen, and therefore define two independent and distinct recombinant microorganisms based upon differences in the nucleotide sequences that encode structurally and functionally different, and distinct end products.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

10. Group I sets forth three structurally and functionally different nucleic acid molecules based upon differing SEQ ID Nos, specifically SEQ Id NO 1, 2 and 6. (claim 1 shows 3 species)

11. Group II sets forth three different species of antibody/immunoglobulin that structurally and functionally differ one from the other:

a. Polyclonal immunoglobulins (claims 2, 3-8, 16-21) (obtained from milk, colostrums or egg yolks; or sera from a mammal (claim 2 recites "antisera") class 424/157.1

b. Monoclonal immunoglobulins (claim 9) obtained through fusion of antibody producing cell with a neoplastic cell line; class 424/141.1

c. Recombinantly produced antibodies (claim 25) contained in a transformed microorganism that is not a neoplastic cell line, wherein the microorganism has been transformed with the genetic material that encodes the antigen-binding region of the monoclonal antibody. Class 530/386.

12. Group III sets forth three different independent and distinct methods of manufacturing an immunoglobulin or antibody, the methods utilizing a different combination of reagents for obtaining the resultant immunoglobulin/antibody composition, the combinations comprising:

d. The immunogen, a cow or chicken for immunization, isolation of serum (claims 10-12) class 424/ subclass 234.1 ;

e. The immunogen, a mouse, fusion reagents, a neoplastic cell line (claim 13) class 435/326;

f. The immunogen, a mouse, fusion reagents, a neoplastic cell line, the genetic material encoding the immunoglobulin/antibody and a recombinant microorganism able to express the antibody (claims 14-15) .class 435/71.1.

13. Group IV sets forth three different independent and distinct methods of using the immunoglobulin or antibody compositions, the methods utilizing a composition that contains a combination of reagents the structurally and functionally define independent and distinct species of immunoglobulin/antibody composition for administration, the combinations comprising:

g. polyclonal (claims 22)(cow or chicken antiserum) that bind to a plurality of epitopes and plurality of binding specificities: class 424, subclass 130.1 or 157.1;

h. monoclonal mammalian antibodies (claim 23, depends from claim 6 which includes the species monoclonal recited in claim 9 which depends from claim 6) that specifically bind to a single epitope and uniformly bind with a single binding specificity; class 424, subclass 141.1;

i. recombinant microorganism able to express an antibody (claim 24) class 424, subclass 133.1.

14. Group V sets forth independent and distinct methods of treating or preventing H.pylori infection based upon the three structurally and functionally different nucleic acid molecules, SEQ Id NO 1, 2 and 6, used to transform the recombinant culture of microorganisms (instant claim 26) class 424, subclass 200.1.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

17. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable
18. thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I). such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

21. In the instant case a burden has been established in showing that the inventions of Groups I-V are classified separately necessitating different searches of issued US Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example DNA(nucleotide sequences) and antibodies are different products. Additionally, it is submitted that the inventions of Groups I-V have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

22. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01..

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
January 24, 2005

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